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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/640,852	08/17/2000	Alissar Nehme	600-41-PA	5392

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EXAMINER

LANDSMAN, ROBERT S

ART UNIT

PAPER NUMBER

1647

DATE MAILED: 03/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .	09/640,852	Applicant(s)	NEHME ET AL.
Examin er	Robert Landsman	Art Unit	1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 28 February 2003.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1,2,5,6,9,10,13-16,19-21,24-27 and 30-45 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1,5,9,13,14,19,24,25,30,31,33,35,37,40 and 43 is/are rejected.

7) Claim(s) 2,6,10,15,16,20,21,26,27,32,34,36,38,39,41,42,44 and 45 is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7.

4) Interview Summary (PTO-413) Paper No(s) _____.

5) Notice of Informal Patent Application (PTO-152)

6) Other: _____

DETAILED ACTION

Upon further examination of the specification and pending claims, the Examiner has withdrawn the finality of the last Office action (mailed 10/24/02; Paper No. 6) and prosecution of the merits continues.

1. Formal Matters

- A. Claims 1-30 were pending in the application. In Amendment B, filed 2/28/03, Applicants canceled claims 3, 4, 7, 8, 11, 12, 17, 18, 22, 23, 28 and 29 and added new claims 31-⁴~~35~~. Therefore, claims 1, 2, 5, 6, 9, 10, 13-16, 19-21, 24-27 and 30-45 are pending and are the subject of this Office Action.
- B. All Statutes not found in this Office Action can be found, cited in full, in a previous Office Action.

2. Claim Objections

- A. All claim objections have been withdrawn in view of Applicants' cancellation of the claims which were substantial duplicates.
- B. Claims 1, 14, 31, 37 are objected to since the syntax could be improved by reciting that "n" is defined as "an integer 0-5." This would also maintain the consistency within the claims. Claims 2, 5, 6, 9, 10, 13, 15, 16, 19-21, 24-27, 30, 32-36 and 38-45 are also objected to since they depend from these claims.

3. Claim Rejections - 35 USC § 112, first paragraph – scope of enablement

- A. The rejection of all claims under 35 USC 112, first paragraph, regarding the scope of the claims as drawn to all malignant diseases, has been withdrawn, in view of Applicants amendments to the claims to limit the malignant diseases to those supported in the specification and the Declaration of Dr. Alissar Nehme, namely breast cancer, colon cancer and leukemia. To make the record clear, it is noted that this Declaration is being treated as a Declaration under 37 CFR 1.132.

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B. Claims 1, 5, 9, 13, 14, 19, 24, 25, 30, 31, 33, 35, 37, 40 and 43 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the use of tazarotene with interferons to produce synergistic effects in cancer cell lines, does not reasonably provide enablement for the use of tazarotene with any other chemotherapeutic agent to produce synergy in these cell lines. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

In In re Wands, 8USPQ2d, 1400 (CAFC 1988) page 1404, the factors to be considered in determining whether a disclosure would require undue experimentation include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

First, the breadth of the claims is excessive. Applicants have only provided guidance and working examples that tazarotene shows synergistic^m only in combination with interferons to inhibition of proliferation of cancerous cells. No guidance or working examples have been provided showing that tazarotene is synergistic with any other chemotherapeutic agent. Furthermore, since synergy is, generally, an unexpected result, it would not have been predictable to one of ordinary skill in the art at the time of the present invention that the use of tazarotene with any other chemotherapeutic agent other than interferons, would have produced a synergistic effect in the disclosed cell lines. Applicants have provided a Declaration by Dr. Alissar Nehme showing that tazarotene shows synergy with 5-FU and SN-38. However, this declaration is not deemed persuasive since, without information regarding theoretical combination curves of tazarotene with any of these compounds, or any information regarding statistical significance, the Examiner cannot determine if, in fact, these compounds show synergy, especially in view of the fact that these graphs provided in the declaration, do not appear to show synergy, but at most, an additive effect.

Therefore, in summary, due to the excessive breadth of the claims regarding the use of tazarotene with chemotherapeutic agents other than interferons to produce synergy in cancer cell lines, along with the lack of guidance and working examples of synergy with any other chemotherapeutic agents and the unpredictability of the occurrence of synergy between two or more compounds, leads the Examiner to conclude that undue experimentation is required to practice the invention as claimed.

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Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (703) 306-3407. The examiner can normally be reached on Monday - Friday from 8:00 AM to 5:00 PM (Eastern time) and alternate Fridays from 8:00 AM to 5:00 PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4242. Fax draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Robert Landsman, Ph.D.

Patent Examiner

Group 1600

March 21, 2003

Gary A. Kunz
GARY KUNZ
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